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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,058	04/02/2004	John E. Baker	BA-32448(1)	2664

22202 7590 05/05/2005

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MILWAUKEE, WI 53202

EXAMINER

MAYER, SUZANNE MARIE

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/817,058

Applicant(s)

BAKER ET AL.

Examiner

Suzanne M. Mayer, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 March 2005.  
2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-46 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-46 are pending in this application.

### ***Priority***

2. Acknowledgment is priority claims to Provisional application 60/460,684 April 4, 2003, which was acknowledged in the previous office action of Nov. 3, 2004, however, acknowledgement was mistakenly drawn to an improper priority date.

### ***Oath/Declaration***

3. The Declaration filed on March 3, 2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the 102(a) Cavillo et al. and 102(e) Stamler et al. references.

The declaration submitted is insufficient because ALL inventors involved in the conception and reduction to practice must sign the declaration. The declaration submitted by Applicant on March 3, 2005 is lacking a signature by all of the inventors and thus is considered defective.

### ***Response to Arguments***

4. No arguments were submitted with respect to the rejections of claims 1-2, 4, 6-16, 18, 24, 29-30, 32-33, 38-40 and 43-46 in view of Cavillo et al. Instead, applicant

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submitted and relied upon the declaration submitted under 131(b) to swear behind the teachings of Cavillo et al.

5. No arguments were submitted with respect to the rejections of claims 1-8, 10-18, 24-31 and 46 in view of Stamler et al. Instead, applicant submitted and relied upon the declaration submitted under 1.131(b) to swear behind the teachings of Stamler et al.

However, as noted above, the declaration relied upon by Applicant is deemed to be defective and thus cannot be used to swear behind the references cited in the previous Office action.

6. Applicant's arguments filed March 3, 2005 to overcome the rejection of claims 32-45 in view of Cynshi (U.S. 4,732,889) have been fully considered but they are not persuasive. The claims are drawn to a pharmaceutical formulation containing EPO. However, no patentable weight of the exact concentration/formulation of EPO in the composition or its intended use is given because it does not materially change the composition. In simpler words, a pharmaceutical composition with 50 U/kg of EPO is not **materially** different from a pharmaceutical composition with 500 u/kg of EPO. Regardless of the exact formulation or intended use, the composition is still a composition of EPO.

7. Applicant's arguments to overcome the 103(a) rejection of claims 19-23 have been fully considered but they are not persuasive. First of all, in view of the defective declaration submitted by Applicant, arguments involving Stamler still stand. Furthermore, applicant suggests that Brines (US 2003/0134798) does not teach or

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suggest treating a donor organ for up to 30 hours. Applicant further points out the following paragraph from Brines, [0069]:

- a. "....Using the solution, preservation may be extended beyond the 30 hour limit recommended for cadaveric kidney preservation."

The examiner acknowledges that Brines does teach that the extension for transplant for an organ given can exceed the normal 30 hour time period by administering EPO to organs. However, this is just one aspect of what Brines teaches, specifically in the first line of paragraph [0069] it is stated:

"In another aspect of the invention a perfusate or perfusion solution is provided for perfusion and storage of organs for transplant, the perfusion solution including an amount of an erythropoietin effective to protect erythropoietin-responsive cells and associated cells, tissues *or organs*."

Thus, the arguments from the previous office action in combination with Stamler et al. the rejection of the previous office action is maintained, because, administration of the EPO prior to transplantation can occur anywhere from 0-30 hours and beyond according to Brines, which still encompasses 5-30 minutes.

### ***Claim Rejections - 35 USC § 112***

8. Applicant's amendment of claim 2 to overcome the indefinite rejection set forth in the previous office action sufficiently overcomes the rejection. Thus the rejection has been withdrawn.

***Claim Rejections - 35 USC § 102***

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
10. Claims 1-2, 4, 6-16, 18, 24, 29-30, 32-33, 38-40 and 43-46 are rejected under 35 U.S.C. 102(a) as being anticipated by Cavillo et al. The rejection was explained in the previous office action.
11. Claims 1-8, 10-18, 24-31 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Stamler. The rejection was explained in the previous office action.
12. Claims 32-45 rejected under 35 U.S.C. 102(b) as being anticipated by Cynshi et al. The rejection was explained in the previous office action and in the response to the arguments in the present Office action.

***Claim Rejections - 35 USC § 103***

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
14. Claims 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stamler in view of Brines et al. The rejection was explained in the previous office action and in the response to the arguments in the present Office action.

***Conclusion***

15. No claim is allowed.

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 8.30am to 5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

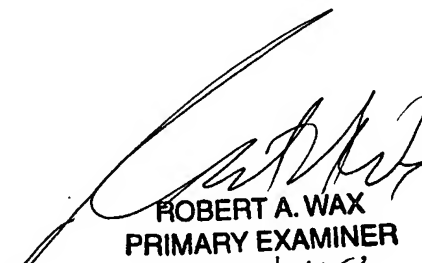
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Smm*

SMM

28 April, 2005

  
ROBERT A. WAX  
PRIMARY EXAMINER  
*Art Unit 1653*